ethylpyridinium chloride (TDEPC); octenidine; delmopinol; octapinol; nisin; zinc ion agent; copper ion agent; essential oils; furanones; bacteriocins; salts thereof; and mixtures thereof.

6. The method of Claim 5 wherein said composition is in a form selected from the group consisting of a mouthrinse, toothpaste, tooth gel, tooth powder, non-abrasive gel, chewing gum, mouth spray, lozenge, and a pet chew product.

7. A method for promoting whole body health in human and other animal subjects according to Claim 5 wherein the composition topically administered to the subjects' oral cavity further comprises an additional therapeutic agent which is a H2-antagonist.

8. A method for promoting whole body health in human and other animal subjects, comprising topically administering to said subjects' oral cavity a composition comprising
   a. a safe and effective amount of an antimicrobial agent selected from the group consisting of stannous ion agent, triclosan, triclosan monophosphate, chlorhexidine, domiphen bromide; cetylpyridinium chloride (CPC), zinc ion agent, copper ion agent, essential oils, and mixtures thereof;
   b. a safe and effective amount of an additional therapeutic agent; and
   c. a pharmaceutically-acceptable topical, oral carrier.

REMARKS

The above amendments are made in response to the Examiner's objections to certain language in the claims as indefinite and to the finality of the restriction requirement to the subgenus of H2 antagonist as the additional therapeutic agent. The claims are also amended to more distinctly define the present invention as a method for promoting whole body health in human and animal subjects by administering to the oral cavity of the subjects a topical composition comprising an antimicrobial agent and optionally a H2 antagonist as additional therapeutic agent.

No new matter is involved with the amendments to the claims and no additional claims fee is known to be due.

By these amendments Claims 5-8 remain pending in the application. Claims drawn to nonelected subject matter that have been withdrawn for consideration at this time will be pursued in a divisional application.

Claims Rejection Under 35 USC § 112

The Examiner has rejected Claims 1-8 under 35 USC § 112, second paragraph, as being indefinite stating that it is not clear what the phrase "whole body health" encompasses. Claims 1-8 are further rejected as indefinite for reciting the phrases "analogs" and "essential", which the Examiner considers as not clear.

Applicants respectfully traverse the Examiner's rejection of the claims as indefinite because of the phrases "whole body health" and "essential." The term "analogs" has been deleted from the claims rendering the Examiner's objection to the term moot.

Applicants submit that the term "essential" as used in the present claims in the phrases "essential oils" and "essential fats" is not indefinite and would be readily understandable to those of skill in the chemical and biochemical arts. The term "essential" is defined for example in a ready reference such as *Hawley's Condensed Chemical Dictionary*, 13th Edition, as follows:

(1) Containing the characteristic odor or flavor, (i.e., the essence) of the original flower or fruit: an "essential" oil, usually obtained by steam distillation of the flowers or leaves or cold-pressing of the skin.

(2) As applied to certain amino acids, fatty acids, and vitamins, this term is used by biochemists to mean that the compound in question is a necessary nutritional factor that is not synthesized within the body of the animal and thus must be obtained from external sources. Eight amino acids are classified as "essential" on this basis.

Under the definition of "fatty acids" in *Hawley's*, is the entry:

"Linoleic, linolenic, and arachidonic acids are called "essential" fatty acids by biochemists because such acids are necessary nutrients that are not synthesized in the animal body."

The definition for "essential oils" in *Hawley's* is as follows:

"A volatile oil derived from the leaves, stem, flower, or twigs of plants, and usually carrying the odor or flavor of the plant. Chemically, they are often principally terpenes (hydrocarbons), but many other types also occur. Essential oils (except for those containing esters) are unsaponifiable. Some are nearly pure single compounds, as oil of wintergreen, which is methyl salicylate. Others are mixtures, as turpentine oil (pinene, dipentene) and oil of bitter almond (benzaldehyde, hydrocyanic acid). Some contain resins in solution and are called oleoresins or balsams."

Additional references on essential oils are *Kirk-Othmer Encyclopedia of Chemical Technology*, 4th Edition and *Essential Oils*, Vol. 1-6 (1948-1952) by E. Guenther.

Applicants also submit that the phrase "whole body health" is clearly defined in the disclosure and refer the Examiner to the definition at page 10, lines 28-32 as follows:

By "whole body health" as used herein is meant overall systemic health characterized by a reduction in risk of development of major systemic diseases and conditions including cardiovascular disease, stroke, diabetes, severe respiratory infections, premature births and low birth weights (including post-partum dysfunction in neurologic/developmental function), and associated increased risk of mortality.

The present invention as now claimed is specific to a method for promoting whole body health or overall systemic health. The method involves topically administering a composition comprising an antimicrobial agent, optionally with an additional therapeutic agent such as a H2 antagonist, to the oral cavity as opposed to systemic administration. The present claims are based on Applicants' discovery of a new use for a method of treatment of the oral cavity. Specifically, Applicants have discovered that topical administration to the oral cavity of compositions comprising an antimicrobial agent is beneficial in promoting systemic health in addition to treating or preventing bacteria-mediated oral cavity conditions. In particular, the present method effectively decreases etiologic factors that contribute to development of certain systemic diseases such as heart disease. By decreasing the etiologic factors for a systemic disease, the risk of developing such a disease is also decreased leading to better overall health for the subject.

Claims Rejection Under 35 USC § 102(b)

Claims 1-8 have been rejected under 35 USC § 102(b) as being anticipated by commonly owned Singer et al. (US 5,364,616). The Examiner contends that the whole body health benefits are inherent in the referenced methods.

Applicants respectfully traverse the Examiner's rejection of the claims in view Singer et al. references as it would apply to method Claims 5-8 as amended herein. Composition Claims 1-4 are withdrawn from consideration at this time.

The present claims define a method for promoting whole body health by topical administration to the oral cavity of a composition comprising a H2 antagonist. The present method promotes whole body health (or overall systemic health) by controlling bacterial-mediated diseases and conditions present in the oral cavity, thereby preventing the spread of oral bacterial pathogens, bacterial toxins and inflammatory mediators/ cytokines into the bloodstream and other parts of the body. These factors are believed to be involved in the etiology of certain systemic diseases including cardiovascular disease, stroke, diabetes, severe respiratory infections, premature births and low birth weights (including post-partum dysfunction in neurologic/developmental function). By reducing these etiologic or causative factors, the risk of development of these systemic diseases is likewise reduced, leading to better whole body health.

For example, it has been known that bacteria may affect the heart and other organs of the body. Now evidence is mounting that suggests people with periodontitis, a bacteria-mediated disease of the oral cavity, may be more at risk for heart disease, and have a significantly higher risk of having a fatal heart attack than patients without periodontitis. One theory to explain the link between periodontal disease and heart disease is that oral pathogenic bacteria enter the blood through inflamed gums, attach to fatty plaques in the coronary arteries (heart blood vessels) and cause small blood clots that contribute to clogged arteries. It has been reported that 70% of the fatty plaque that blocks carotid arteries and causes stroke contain bacteria. Forty percent of those bacteria have been traced to the mouth. Coronary artery disease is characterized by a thickening of the walls of the coronary arteries due to the buildup of fatty proteins. Blood clots can obstruct normal blood flow, restricting the amount of nutrients and oxygen required for the heart to function properly. This may lead to heart attacks. Another possibility is that changes in systemic inflammatory mediators caused by periodontitis increase development of atherosclerotic plaque, which then contributes to thickening of the arterial walls.

By the present claimed method, spread into the bloodstream and other parts of the body of pathogenic bacteria and associated harmful substances including toxins and endotoxins is prevented or minimized. The result is a decrease in the causative factors for certain diseases and a corresponding decrease in the risk of development of these systemic diseases, such as heart disease. Thus, the present claims are directed to a new use for a method that traditionally has been used solely for locally treating or preventing bacteria-mediated diseases and conditions of the oral cavity.

Applicants respectfully submit that the present method claims directed to a new use of topical administration of an antimicrobial agent optionally with a H2 antagonist are novel and unobvious in view of the cited reference. There is no disclosure nor any suggestion in Singer et al. with regard to whole body or systemic health, much less that the present antimicrobial containing compositions administered topically to the oral cavity would promote whole body health by decreasing causative or risk factors that are involved in the development of certain systemic diseases. The benefits to systemic health when the method of treatment is by topical

administration and not by systemic administration have not been appreciated in Singer et al. nor in any other prior disclosure. The present methods are based on the discovery that topical administration of an antimicrobial agent affords unanticipated benefits for preventing oral pathogens and their products from entering into the systemic circulation and from prompting the systemic inflammatory mechanisms and complications that contribute to systemic diseases/disorders such as atherosclerosis, stroke, diabetes, and low birth weight infants.

Applicants also traverse the Examiner's contention that the present method claims are not patentable because the results of the claimed methods, i.e., "whole body health benefits", are inherent. The present method claims fall within the definition under 35 USC. § 100(b) for a patentable "process" (under § 101) which means process, art or method, and includes a ***new use of a known process, machine, manufacture, composition or matter or material.*** (emphasis added). Thus, "a process or method which involves only a new use of an old material is patentable." See *Howes v. Great Lakes Press Corp.*, 679 F.2d 1023, 1029 (2d Cir.), which found that Howes' claim to a method which makes possible the faithful transfer of color art work to fabric by means of treated heat transfer paper was patentable because Howes created a *new use of a known process*. Similarly, ***claims drawn to a method for using either an old or "obvious" composition, wherein the method has unobvious beneficial or useful effects, have been found patentable even though the composition itself could not be patented.*** [*In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977); *In re Legator*, 53 CCPA, 729, 352 F.2d 377 (1965); *Joseph Bancroft & Sons Co. v. Watson*, 170 F. Supp. 78 (D.D.C. 1959), 120 USPQ 265].

Clearly, the issue relevant to the patentability of the present methods is whether or not the claimed new use is obvious to one of skill in the art. Applicants submit that the present claimed methods have unobvious beneficial and useful effects of promoting whole body health. That this benefit might be inherent "***is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result.***" [*In re Floyd E. Naylor*, 54 CCPA 902, 369 F.2d 765 (1966), 152 USPQ 106; *In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977].

CONCLUSION

Applicants respectfully request reconsideration of this application, entry of the amendments, withdrawal of the 35 USC §112, first paragraph rejection, withdrawal of the claims rejections under §102(b) and allowance of all application claims.

Attached hereto is a marked-up version of the changes made to claims by the current amendments. The attached page is captioned "**Version With Markings to Show Changes Made**".

Respectfully submitted,

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Version With Markings to Show Changes Made

Claims 1-4 are canceled without prejudice. Method Claims 5-8 are amended as follows. Claim 5 is presented in independent format and Claim 7 is now dependent from Claim 5. Claim 6 is amended to be in Markush format. Reference to the different classes of additional therapeutic agent in Claim 8 has been deleted.

5. (Twice amended) A method for [treating and preventing oral cavity diseases in human and other animal subjects and thereby] promoting whole body health in [said] and other animal subjects, comprising topically administering to said subjects' oral cavity, a composition [according to Claim 1] comprising a safe and effective amount of an antimicrobial agent and a pharmaceutically acceptable oral carrier, wherein said antimicrobial is selected from the group consisting of stannous ion agent; triclosan; triclosan monophosphate; chlorhexidine; alexidine; hexetidine; sanguinarine; benzalkonium chloride; salicylanilide; domiphen bromide; cetylpyridinium chloride (CPC); tetradecylpyridinium chloride (TPC); N-tetradecyl-4-ethylpyridinium chloride (TDEPC); octenidine; delmopinol; octapinol; nisin; zinc ion agent; copper ion agent; essential oils; furanones; bacteriocins; salts thereof; and mixtures thereof.

6. (Twice amended) The method of Claim 5 wherein said composition is in a form selected from the group consisting of a mouthrinse, toothpaste, tooth gel, tooth powder, non-abrasive gel, chewing gum, mouth spray, lozenge, and a pet chew product.

7. (Twice amended) A method for [treating and preventing oral cavity diseases in human and other animal subjects and thereby] promoting whole body health in [said] human and other animal subjects according to Claim 5, [comprising topically administering to said subjects' oral cavity, a composition according to Claim 3] wherein the composition topically administered to the subjects' oral cavity further comprises an additional therapeutic agent which is a H2-antagonist.

8. (Twice amended) A method for [treating and preventing oral cavity diseases in human and other animal subjects and thereby] promoting whole body health in [said] human and other animal subjects, comprising topically administering to said subjects' oral cavity a composition comprising
   a. a safe and effective amount of an antimicrobial agent selected from the group consisting of stannous ion agent, triclosan, triclosan monophosphate, chlorhexidine, domiphen bromide; cetylpyridinium chloride (CPC), zinc ion agent, copper ion agent, essential oils, and mixtures thereof;
   b. a safe and effective amount of an additional therapeutic agent [selected from the group consisting of anti-inflammatory agents, H2-antagonists, metalloproteinase inhibitors, cellular redox modifiers, and mixtures thereof]; and
   c. a pharmaceutically-acceptable topical, oral carrier.